VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 11/12/08

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Richard Harvie, R. Ph.
Norman Ward, M.D.
Kathleen Boland, Pharm.D.
Cheryl Gibson, M.D.
Stuart Graves, M.D.

Staff:

Nancy Hogue, Pharm.D. (MHP)
Stacey Baker, OVHA
Judy Jamieson, OVHA
Robin Farnsworth, OVHA
Nancy Miner, (MHP)

Guests:

Carl Pepe, GSK
Lyndon Braun, Santarus
Matt Badalucco, Merck
Michael Deorsey, Abbott
Pamela DiPerrio, GSK
Paul Kelly, Janssen
Rod Francisco, Forest
Scott Mosher, GSK
Shannon Partenza, Takeda
Tom Martin, Boehringer-Ingelheim
Tracy Wall, Merck

Michael Scovner, M.D. Chair, called the meeting to order at 7:00 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The October 2008 meeting minutes were accepted as printed.

3. OVHA Pharmacy Administration Updates:

- No update this month.

4. Medical Director Update: Medical Director Absent

- Clinical Programs Update: None to report.
- Prescriber Comments: None to report.

5. Follow-up items from Previous Meeting:

- No Follow-up items

6. **Clinical Update: Drug Reviews:** *Nancy Hogue, Pharm.D. MedMetrics Health Partners(MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update unless otherwise noted.

- Cimzia® (certolizumab pegol) Subcutaneous Injection: Recommended for addition to the PDL as preferred after clinical criteria are met in the Crohn's Disease Injectable category, so Prior Authorization would be required. Coverage would require that the patient has a diagnosis of Crohn's disease and has already been stabilized on the medication, or the diagnosis is moderate to severe Crohn's disease and at least 2 of the following drug classes resulted in an adverse effect, allergic reaction, inadequate response, or treatment failure (i.e. resistant or intolerant to steroids or immunosuppressants): aminosalicylates, antibiotics, corticosteroids, and immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate. Of note: Cimzia® has been shown to be effective in patients who have been treated with infliximab but have lost response to therapy.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Patanase® (olopatadine) Intranasal Spray: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the diagnosis or indication for the requested medication is allergic rhinitis and the patient has had a documented side effect, allergy, or treatment failure to loratadine (OTC) or cetirizine OTC or a preferred nasal glucococorticoid. A quantity limit of 1 bottle/month was recommended.

Public Comment: No public comment.

Board Decision: The Board approved the recommendations as described but requested that patients fail both loratadine or cetirizine and a preferred nasal glucocorticoid. These same criteria should be applied to Astelin® as well.

7. **Annual Review of Clinical Coverage Criteria:** *Nancy Hogue, Pharm.D. (MHP)*

(Public comment prior to Board action)

- Anti-hyperkinesis and Anti-narcolepsy: No changes proposed to this category. The Clinical Criteria Manual table presented included some small modifications in order for it to read more clearly.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Anti-anxiety: Anxiolytics: The category was divided into benzodiazepine and non-benzodiazepine products in order to be easier to read. Hydroxyzine was added to the non-benzodiazepine sub-category. Generic names were added to the drug listings. There were no changes to preferred or non-preferred products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the sub-divided category as presented.

- Sedative/Hypnotics: Benzodiazepine: No changes proposed to this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Sedative/Hypnotics: Non-Benzodiazepine/Non-Barbiturate: It was recommended that Lunesta® move to a non-preferred status with a "grandfathering" of current users and that generic zaleplon move to preferred status to offer an additional choice for prescribers. It was proposed that these changes become effective 1/1/09. Quantity limits for zaleplon and Sonata® were also proposed. The class was renamed to clarify that it also does not include barbiturates.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Antidepressant Class Reviews
    - Miscellaneous – no changes recommended
    - SNRIs – no changes recommended
    - SSRIs – brand Luvox® removed as no longer available
    - Tricyclics & MAOIs – updated language, FDA maximum recommended doses and generic names added throughout.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

8. <u>New Drug Classes:</u> *Nancy Hogue, Pharm.D. (MHP)*

- Testosterone: Topical: It was recommended that preferred products be AndroGel® Gel and AndroGel® Gel Pump. Non-preferred topical testosterone agents will be Androderm® and Testim® Gel. For approval of Androderm® or Testim®, a trial of AndroGel® would be required. Quantity limits were proposed for all products (preferred and non-preferred).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above and requested that current Androderm® users be grandfathered.

9. <u>RetroDUR:</u>

No RetroDUR this month.

10. <u>New Drug Product Plan Exclusions</u>: (Consent Agenda Topic)

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or

very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 10/09/08 - 11/06/08. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Nancy Hogue, Pharm.D. (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

12. General Announcements: *Nancy Hogue, Pharm.D. (MHP)*

FDA Safety Alerts

- Over the Counter Cough and Cold Medications: The FDA notified healthcare professionals and consumers that the Consumer Healthcare Products Association (CHPA) is voluntarily modifying the product labels for consumers of over the counter (OTC) cough and cold medicines to state "do not use" in children under 4 years of age. It was recommended that the alert be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

- Raptiva® (efalizumab) – life-threatening infections: The FDA notified healthcare professionals of extensive labeling changes, including a Boxed Warning, to highlight the risks of life-threatening infections, including bacterial sepsis, viral meningitis, invasive fungal disease, progressive multifocal leukoencephalopathy and other opportunistic infections with the use of Raptiva®. In addition, the prescribing information will be updated to describe a potential risk for the permanent suppression of the immune system with repeat administration of Raptiva® in children. Raptiva® is not approved for children under 18 years of age. The communication will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 7:40 p.m.

Next DUR Board Meeting
Tuesday, December, 09 2008
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.